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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,077	09/22/2003	K.T. Venkateswara Rao	ACS 63118 (3624X)	1259

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EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,077

Applicant(s)

RAO, K.T. VENKATESWARA

Examiner

Bruce E. Snow

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
4a) Of the above claim(s) 3,5,7,8 and 19-25 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,2,4 and 9-18 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 8/22/06 have been fully. Regarding the IDS dated 9/1/04, wherein the 1499 is missing, the Examiner knows nothing more and cannot speculate on the intended listing of references.

The rejections under 35 U.S.C. 112, second paragraph, have been clarified and have been withdrawn. It is noted that claim 17 is not claiming the stent; this clarification necessitated a new rejection in view of Ding et al.

Regarding the rejection under 35 U.S.C. 102(b) as being anticipated by Tartaglia et al (5,700,286), applicant states that the drug loaded elements are not independent. It is the Examiner's position that the slits 30 produce independent elements even though they are attached at a first end. Applicant's claim language does not exclude this configuration. The free ends are allowed to move **independent** from the others and are therefore considered independent. Tartaglia states, "*the film of polymeric material also has a free end 28, and can have one or more slits 30 in the polymeric film transverse to the axis 32 of the stent to accommodate possible uneven expansion of the underlying stent structural member (4:37 et seq.)*". Regarding applicants second argument, note that in this quotation there is nothing about the sleeve stretching; it is the Examiners position that it slides and/or unrolls.

Regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Williams (5,707,385) in view of Tartaglia et al (5,700,286), the Examiner respectfully disagrees with applicant, the membrane does not have to stretch when the stent is

Art Unit: 3738

expanded; as noted, column 2, lines 30-41 state "sliding or stretching". Regarding the argument about independent elements, see the Examiner's position above.

Applicant's arguments regarding the rejection under 35 U.S.C. 103(a) as being unpatentable over Williams (5,707,385) in view of Layne et al where persuasive; said rejection has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Art Unit: 3738

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 17 is rejected under 35 U.S.C. 102(e) as being anticipated by Ding et al (2006/0089705).

17. (currently amended) A sleeve 10 loaded with at least one therapeutic drug for the eventual release thereof at a treatment site within a body lumen, comprising:

a prefabricated patterned tubular sleeve portion having independent drug-loaded elements 12-15 completely detached from an outer surface of a stent structure in an unexpanded condition (note this is merely functional language in which the device is fully capable of because the stent is not being positively claimed), the independent drug-loaded elements loaded into the patterned tubular sleeve portion being decoupled from the outer surface of the stent while the stent is in an expanded condition so that the independent drug-loaded elements are held against the body lumen (functional language), wherein the sleeve is not stretched when the stent structure expands from the unexpanded condition to the expanded condition.

Claims 1, 2, 6, and 9-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Tartaglia et al (5,700,286).

17. (currently amended) A sleeve loaded with at least one therapeutic drug for the eventual release thereof at a treatment site within a body lumen, comprising:

a prefabricated patterned tubular sleeve portion having independent drug-loaded elements 4 completely detached from an outer surface of a stent structure in an

Art Unit: 3738

unexpanded condition, the independent drug-loaded elements loaded into the patterned tubular sleeve portion being decoupled from the outer surface of the stent 2 while the stent is in an expanded condition so that the independent drug-loaded elements are held against the body lumen, wherein the sleeve is not stretched when the stent structure expands from the unexpanded condition to the expanded condition.

Claims 1, 2, 9-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Tartaglia et al (5,700,286).

Tartaglia et al teaches a sleeve loaded with at least one therapeutic drug for the eventual release thereof at a treatment site within a body lumen, comprising:

a prefabricated patterned tubular sleeve portion (generally element 5) having independent drug-loaded elements separated by slits 30, the tubular sleeve being releasably attached to an outer surface of a stent structure 22 in an unexpanded condition (via friction), at least a portion of the patterned tubular sleeve portion being decoupled from the outer surface of the stent when the stent is in an expanded condition so that the independent drug-loaded elements are held against the body lumen by at least a portion of the patterned tubular sleeve portion.

Regarding claim 1 and 18, the stent is interpreted as being positively claimed.

Regarding claim 9, the claim only claims a portion of the sleeve has to be unattached in the unexpanded and expanded condition which a portion clearly is.

Claim 12 is interpreted as describing the struts of the stent.

Claim 15, the same materials inherently have the same characteristics.

Art Unit: 3738

Regarding claim 17, for this rejection the Examiner has interpreted the claim as not positively claiming the stent. Therefore, the sleeve by itself before it is connected to the stent is fully capable of fulfilling the claim language. Additionally, the claim is claiming only portion of the sleeve has to be unattached in the unexpanded condition and the expanded condition which it clearly is.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims are 1, 2, 4, and 9-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (5,707,385) in view of Tartaglia et al (5,700,286).

Williams teaches a sleeve loaded with at least one therapeutic drug for the eventual release thereof at a treatment site within a body lumen, comprising:

a prefabricated patterned tubular sleeve portion 5 being releasably attached to an outer surface of a stent structure in an unexpanded condition, at least a portion of the patterned tubular sleeve portion being decoupled from the outer surface of the stent when the stent is in an expanded condition. However, Williams is silent regarding the sleeve having independent drug-loaded elements. Tartaglia et al teaches a similar sleeve comprising independent elements separated by slits 30. It would have been obvious to one having ordinary skill in the art to have utilized the slits 30 of Tartaglia et

Art Unit: 3738

al on the tubular sleeve of Williams "to accommodate possible uneven expansion of the underlying stent structural member (4:40-41)".

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E. Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone

Art Unit: 3738

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes

A handwritten signature in black ink, appearing to be 'BS' with a large loop and a trailing line.

BRUCE SNOW
PRIMARY EXAMINER